



UNITED STATES PATENT AND TRADEMARK OFFICE

Handwritten signature

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,965	07/28/2003	Manfred Keller	BHE 3.0-109 (CONT)	6183
35437	7590	02/21/2006		
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO 666 THIRD AVENUE NEW YORK, NY 10017			EXAMINER HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER

1616

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,965

Applicant(s)

KELLER ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/05 has been entered.

Receipt is acknowledged of the Amendments and Remarks filed on 09/22/05. Claims 22, 43, 44, 58 and 59 are amended and new claims 62-68 are added. Accordingly claims 22-68 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is vague and indefinite for reciting a relative term. The term "reduced" in claim 22 is a relative term which renders the claim indefinite. The term "reduced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 32 is indefinite because it is not clear if the Markush type group includes a) and b) or if the group includes agents in a) and also a corticosteroid.

Claim 43 is indefinite because the statement "stabilizing against penetrating moisture a fine particle fraction of a dry powder formulation" is confusing and not clear. It is not clear if the method is to stabilize the formulation or the FPF.

Claim 44 is vague and indefinite because it is not clear how a dry powder **inhaler** can have a reduced moisture sensitivity.

The term "improved" in claim 58 is a relative term which renders the claim indefinite. The term "improved" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Remaining claims are rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 44-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth (Respiratory Drug Delivery II) in view of Carling (WO 9311773).

Staniforth discloses delivery of powders to respiratory tract, where the particles have a diameter of from about 1 to 3 micron (see page 532, lines 6 and 15-16). The

Art Unit: 1616

particles are said to be adhered to a large carrier particle of the size 200 micron (page 536, lines 20-23).

Staniforth discloses that additives such as magnesium stearate and talc are added to the fine particles adhered to coarse carrier particles of sucrose crystals (see page 546, lines 8-14). Staniforth teaches active particles such as salicylic acid, but lacks disclosure on other active agents.

Carling teaches formulations of formoterol (as a fumarate dehydrate) and budesonide for inhalation in the treatment of respiratory disorders (abstract). The formulations may be in the form of a dry powder and administered by a dry powder inhaler (page 6, lines 31-36). The carrier such as lactose, dextran or glucose and other additives are added to the powder formulation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Staniforth of powder formulations comprising an active agent in small particle size and a carrier particle in large size and magnesium stearate as an additive, to have looked in the art for specific active agents with reasonable expectations of successfully preparing effective dry powder formulations comprising of the active agents which can be used in treating other respiratory disorders and other patients.

Response to Arguments

Applicant's arguments filed 09/22/05 have been fully considered but they are not persuasive with regard to claims 44-64.

Applicant argues that Staniforth is concerned with the preparation of agglomerates of particles that optimally break up into primary particles, particularly on entering the airways of the lungs. Applicant also argues that according to Staniforth, the addition of magnesium stearate disrupts bonding and liberates the drug particles at reduced removal forces. However this is not persuasive with regard to formulation claims, because regardless of the function of magnesium stearate stated in Staniforth's reference, both powder formulations comprise magnesium stearate and an active agent with large carrier particles. Here the function of magnesium stearate is not given weight.

Applicant argues that Carling teaches a combination therapy for the treatment of respiratory disorders. However there is no remote teaching or suggestion in Carling to use magnesium stearate in admixture with the other ingredients in the formulation for inhalation to reduce moisture sensitivity. This is not persuasive because as stated above the composition formulation only need to have prior art meeting their ingredients and the functions of such ingredients are not given weight. It is also noted that Carling is a secondary art, submitted to show that use of powdered formoterol fumarate in dry powder inhalers is well known. In an obviousness rejection the secondary prior art discloses what the primary prior art lacks. Here Staniforth teaches the formulations comprising magnesium stearate. Carling teaches specific active agents of the instant

Art Unit: 1616

claims. Substituting one active for another in various formulations and dosage forms is well known and widely practiced.

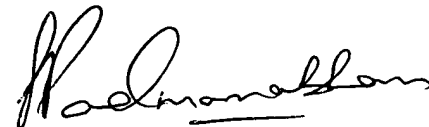
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
February 15, 2006



GREEN PADMANABHAN
SUPERVISORY PATENT EXAMINER